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EXAMINER	
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ART UNIT	PAPER NUMBER
1631	23

DATE MAILED: 09/25/01

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

### ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☒ is extended to run 4 months or continues to run \_\_\_\_\_ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 9/11/01 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
  - ☒ They raise new issues that would require further consideration and/or search. (See Note).
  - ☐ They raise the issue of new matter. (See Note).
  - ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: the proposed amdt would raise the new issues of what continuing of binding affidavit of prior recognition suits has an effect compared to previous clm not really any such selectivity as also argued. This would require further consideration and/or search.

2. ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☒ will not be entered and the status of the claims will be as follows:

Claims allowed: none  
Claims objected to: none  
Claims rejected: 28, 29, and 49

However;

- ☒ Applicant's response has overcome the following rejection(s): the 112 2nd para. is based on an artificial basis for TBA + clm 29 as in issue. Also the obj due to Figure designation is overcome. Figure of record due to the above non-obj of the amdt & this deemed still applicable. Further response to arguments is attached.
4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because of reasons of record due to the above non-obj of the amdt & this deemed still applicable. Further response to arguments is attached.
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.  
☐ Other

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Further Explanation of Item 4 on the attached Advisory Action:

The NEW MATTER rejection of claims 28 and 29 and corresponding rejection under 35 U.S.C. § 112, second paragraph, are maintained from the final action, mailed 5/7/01. These rejections were argued in that applicants point to specification sections regarding double stranded nucleic acid target practice. Consideration of each of these sections has failed to reveal written description of double stranded target nucleic acid practice such as genomic DNA segments, for example. In the first section argued by applicants at page 38, lines 9-11, therapeutic and diagnostic utilities are generically stated but without any definition or focus on what target(s) would be meant thereby. There is especially lacking any particularity directed to double stranded target nucleic acids. The next section pointed to by applicants is on page 38, lines 9-28. Applicants note that TBAs bind to targets such as HIV-LTR etc. but without indicating that a probe is also utilized for this binding. Consideration of this section reveals a lack of specificity as to the form of the target(s) that are bound. That is, there is no written description of single versus double stranded target characterization. It is noted that the instant specification on pages 5-7 in the section entitled "Brief Summary of the Invention" completely and only discloses the formation of complexes wherein probes and other more complex assemblies characterize the invention. In light of this summary, the

section on page 38, lines 9-28, reasonably is directed to generic characterization of target(s) for the invention without defining detailed mechanistic features such as the detailed binding structures which are, however, significantly detailed on said pages 5-7. In other words, there are no reaction details disclosed on said page 38. The double-stranded nature of a target without probe complexation practice is not specifically described on said page 38. Applicants argue that said page 38 lacks description of probe usage. In response neither probe usage nor double strandedness of target(s) are disclosed on page 38. Applicants then point to page 44, lines 20-30, regarding another citation which discloses TBA binding without probes. In response, as above neither probe practice nor double strandedness of target(s) are disclosed in page 44 citation. Applicants then argue that Figures 13-15 disclose double stranded target practice. Consideration of said Figures 13-15 reveals that these Figures either depict probe usage for complex formation or alternatively are schematic representations of binding reactions without any specific mechanistic details such as single versus double strandedness of targets. Applicants then argue that the citation of HIV-LTR inherently includes the knowledge in the art that this HIV-LTR structure is double-stranded and cite Lewin at pages 1039-1040. This well known argument for important nucleic acid targets in HIV is confusing in that it is also well known that expression and/or replication of genomic DNA such as

including HIV-LTR segments requires denaturation, at least locally for these well known functions. Thus, genomic DNA as well as virus sequences such as in HPV or HIV-LTR sequences are sometimes single stranded as well as sometimes double stranded. Thus, this argument is also non-persuasive as to what target practice per se is meant by applicants and lacks double stranded target disclosure. One interpretation is that the arguments of applicants is actually that there is suggestion that target(s) is(are) double stranded as an obvious option. In response, it is noted that obviousness is not sufficient support to satisfy the requirements for written description. Lastly, it is again noted that the above cited "Brief Summary of the Invention" is very focused on probe/target complexation as the mechanism for the binding reactions of the invention thus supporting the maintaining of this rejection. The 35 U.S.C. § 112, second paragraph, rejection is not separately argued from the above NEW MATTER rejection except for a brief allegation that someone of skill in the art would understand the metes and bounds of the invention. This allegation is insufficient in overcoming the rejection in that it does not point to specifics or argue the specifics of the rejection.

The rejection of claim 28 under 35 U.S.C. § 103(a) based on Frankel et al. is maintained. This rejection is firstly argued regarding the proposed amending which is directed to specificity of binding or targeting. This is non-persuasive in that the

amendment has been denied entry thus leaving the rejection supported as previously set forth. Even if the amendment had been entered, this rejection would not be overcome by this argument. This is because the reference has a recited specificity of certain targets over non-targets and thus contains the necessary *prima facie* case regarding specificity. Applicants have not indicated why the specific binding to E2 sites is not a specificity as claimed or proposed to be claimed in that there is no claim limitation that has been set forth wherein selectivity as specific as being particular E2 sites per se is required in the instant claim 28. Applicants then set forth a previous examiner's reasons for allowance. In response this reasons for allowance indicates that stabilizing "perfect" hybrids versus potential hybrids with one or more mismatch is the basis for the novelty and non-obviousness. None of this particular specificity is claimed herein and thus this is insufficient to distinguish the reference from the instant invention.

The rejection of claim 49 under 35 U.S.C. § 103(a) based on Essigmann et al. is maintained. This rejection is solely argued regarding the content of non-nucleic acid recognition units in the reference. This is non-persuasive because the open claim language term "comprising" is present in claim 49 regarding the content of the TBA(s) thus being inclusive of other entities as in Essigmann et al. In the TBA therein described.

No claim is allowed.

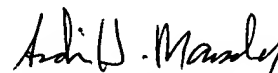
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 24, 2001

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER